

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
10 February 2005 (10.02.2005)

PCT

(10) International Publication Number
WO 2005/011638 A2

(51) International Patent Classification⁷: **A61K 9/20**, 31/40

(21) International Application Number:
PCT/CZ2004/000045

(22) International Filing Date: 5 August 2004 (05.08.2004)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
PV 2003-2135 5 August 2003 (05.08.2003) CZ
PV 2004-857 3 August 2004 (03.08.2004) CZ

(71) Applicant (for all designated States except US): **ZEN-
TIVA, A. S.** [CZ/CZ]; U kabelovny 130, Dolni Mecholupy,
102 37 Praha 10 (CZ).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **SEBEK, Pavel**
[CZ/CZ]; Radcina 12/521, 161 00 Praha 6 (CZ). **PROKOPOVA, Alena** [CZ/CZ]; Bulharska 12, 101
00 Praha 10 (CZ). **SVOBODA, Eduard** [CZ/CZ]; Chud-
nicka 1060, 102 00 Praha 10 (CZ). **RADL, Stanislav**
[CZ/CZ]; Pertoldova 3380, 143 00 Praha 2 (CZ). **STACH,**
Jan [CZ/CZ]; Slitrova 2006, 190 00 Praha 9 - Ujezd
nad Lesy (CZ). **SVOBODA, Martin** [CZ/CZ]; Gocarova
551, 553 41 Lazne Bohdanec (CZ). **KOVACIK, An-
drej** [SK/SK]; Manckovicova 7, 920 01 Hlohovec (SK).
DANKO, Adrian [SK/SK]; Koplotovce 187, 920 01 Hlo-
hovec (SK). **PETRO, Roman** [SK/SK]; Kopernikova 3,
920 01 Hlohovec (SK). **STRIZINEC, Miroslav** [SK/SK];
Hviezdoslavova 28, 920 01 Hlohovec (SK).

(74) Agents: **JIROTKOVA, Ivana** et al.; Rott, Ruzicka &
Guttmann, Patent, Trademark & Law Office, Nad Stolou
12, 170 00 Praha 7 (CZ).

(81) Designated States (unless otherwise indicated, for every
kind of national protection available): AE, AG, AL, AM,

AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN,
CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI,
GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE,
KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD,
MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG,
PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM,
TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM,
ZW.

(84) Designated States (unless otherwise indicated, for every
kind of regional protection available): ARIPO (BW, GH,
GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM,
ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM),
European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI,
FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI,
SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ,
GW, ML, MR, NE, SN, TD, TG).

Declaration under Rule 4.17:

— as to the applicant's entitlement to claim the priority of the
earlier application (Rule 4.17(iii)) for the following desig-
nations AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW,
BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ,
EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID,
IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU,
LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ,
OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY,
TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM,
ZW, ARIPO patent (BW, GH, GM, KE, LS, MW, MZ, NA,
SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ,
BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE,
BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE,
IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI patent
(BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE,
SN, TD, TG)

Published:

— without international search report and to be republished
upon receipt of that report

For two-letter codes and other abbreviations, refer to the "Guid-
ance Notes on Codes and Abbreviations" appearing at the begin-
ning of each regular issue of the PCT Gazette.

(54) Title: **METHODS FOR THE STABILIZATION OF ATORVASTATIN**

(57) Abstract: Stabilization of the pharmaceutical active solid substance atorvastatin alone or in a mixture with other solid sub-
stances embedded in a gaseous mixture is carried out in such a manner that in the surrounding gaseous mixture a partial pressure
of oxygen of at most 2 kPa, preferably less than 1 kPa, more preferably less than 0.4 kPa is maintained. The corresponding partial
pressure is achieved either by use of oxygen absorbers, by packaging under a pressure of 0.3 - 10 kPa, or by packaging under a slight
overpressure of an inert gas, preferably nitrogen, the gas being introduced, by means of nozzles, into the cavities, optionally also
into the space of the press roller and of the wiper station.



WO 2005/011638 A2